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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/531,822	10/24/2005	Mark Brister	PA1187	3938

28390 7590 06/28/2006

MEDTRONIC VASCULAR, INC.
IP LEGAL DEPARTMENT
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EXAMINER	
ADAMS, AMANDA S	

ART UNIT	PAPER NUMBER
3731	

DATE MAILED: 06/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/531,822	BRISTER, MARK	
	Examiner	Art Unit	
	Amanda Adams	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 April 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 April 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/18/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement filed April 18, 2005 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 6-10 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Ragheb et al (US 6,096,070).

3. Ragheb et al disclose a device comprising a stent with discrete first and second regions, a first coating section on the first region, a second coating section on the second region wherein the first and second coating sections comprise first and second polymers, respectively (column 13, lines 16-21, and [18], [18']), the first and second coating sections include a first and second therapeutic agent (column 16, line 20), and the first and second regions form a pattern (column 18, lines 21-27). According to the applicant's specification, the polymers and therapeutic agents may be different or the same as long as they are applied on discrete regions of the stent.

4. Claims 11, 13-17 and 18, 20, and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Castro et al (US 6,616,765).

5. Regarding claims 11 and 18, Castro et al disclose a method for producing a coated stent that provides a stent wherein a first and second region can be arbitrarily defined (column 6, lines 37-38; see also column 8, lines 8-10 where it is disclosed that discrete regions can be defined), mixing a first polymer and first therapeutic agent with a first solvent to form a first polymer solution (column 11, lines 8-12), applying the solution to form a first coating section (applied with nozzle [26]), and repeating this process with a second polymer, a second therapeutic agent, a second solvent, and a second coating section (column 11, lines 55-59).

6. Regarding claims 13 and 20, Castro et al disclose curing the polymer solutions (column 9, lines 64-67).

7. Regarding claims 14-17 and 21, Castro et al disclose mounting the stent in a coating fixture which is a computerized numerically controlled machine (column 7, lines 12-36), and spraying the first polymer solution on the first region by spraying, inkjet spraying, or inkjet printing (column 7, lines 42-45).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ragheb et al (US 6,096,070) in view of Sahota (US 2003/0181973).

10. Ragheb et al disclose the invention substantially as claimed above, but fail to disclose a stent delivery device. However, it is old and well-known in the art to use a stent delivery device to deliver a stent into the vascular system. Sahota teaches a stent delivery system including a catheter with balloon attached to the distal end of it, wherein the stent is disposed on the balloon (paragraphs 43 and 50). A stent delivery system such as this will help deploy a stent intravascularly, and in some cases balloon expansion can even help deploy the delivery of drugs to the vessel. Therefore it would have been obvious to use a stent delivery system such as the one taught by Sahota to insert and expand the stent.

11. Claims 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ragheb et al (US 6,096,070) in view of Richter (US 2002/0010505).

12. Regarding claim 23, Ragheb et al disclose the invention substantially as claimed above except for failing to disclose that the discrete first and second regions are separated by a bare section. However, Richter teaches a stent that has a coating on two discrete regions that are separated by an uncoated region (figure 3A). Separation of coated regions such as this allow delivery of therapeutic substances to specifically designated areas of the blood vessel. Therefore, it would have been obvious to apply a therapeutic substance such as those disclosed by Ragheb et al in the discrete regions separated by a bare region as shown in the device of Richter.

13. Regarding claims 24 and 25, due to lack of criticality in the applicant's specification, the distances between discrete coated regions serve no particular purpose and provide no additional benefit as opposed to any other specific distances. Therefore, it would have been obvious to arbitrarily choose these distances because they are both within the scope of the size of an intravascular stent.

14. Claims 12 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Castro et al (US 6,616,765) in view of Richter (US 2002/0010505).

15. Castro et al disclose the invention substantially as claimed except for failing to disclose applying the first and second polymers to their respective regions of the stent simultaneously. However, Richter teaches a method of applying a coating, referred to as masking, whereby the coating can be simultaneously applied to multiple portions of the stent (paragraph 27). This shows that it is old and well-known to apply a coating to more than one region at a time, and can be used even when the coatings are applied by other methods, and when the coatings are therapeutic agents mixed with polymers and solvents, so that a stent can deliver the therapeutic agents to the appropriate part of a vessel in relation to the stent. Therefore it would have been obvious to coat more than one region at a time with a therapeutic agent mixed with a polymer, also in order to provide a more efficient method of manufacturing.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda Adams whose telephone number is (571) 272-

5577. The examiner can normally be reached on M-F, 8:00am-5:00pm, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

asa ASA 6/20/06

GLENN K. DAWSON
PRIMARY EXAMINER